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EXAMINER	
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ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/007,393	HOCHMAN ET AL.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/27/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed March 27, 2006. The Examiner acknowledges the amendments to claims 1, 14 and 16-19. Claims 1-19 are pending.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "antenna" as claimed in claims 1, 14 and 16-19 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 16-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 16, upon further review of Applicant's disclosure, the original disclosure of the instant application fails to provide support in full, clear, concise and exact terms that the combination probe, transceiver, and power source is *non-expandable and non-compressible in cross-section*. The paragraph spanning lines 7-15 of page 5 provides the only disclosure of the construction of the unit 21 which is believed to be consistent with the claimed combination probe, transceiver and power source. This paragraph only recites that the unit is sealed and made of plastic or polycarbonate. There is no explicit disclosure that the unit 21 is non-expandable and non-compressible in any fashion, nor does the original disclosure even suggest that the unit 21 is rigid. It is

entirely possible that a sealed, plastic unit be at least one of expandable and compressible in cross section. Therefore, this limitation comprises impermissible new matter.

Regarding claims 17-19, the original disclosure of the instant application fails to provide support in full, clear, concise and exact terms that the combination probe, transceiver, and power source is *insertable into a vagina without the use of a tool.* The paragraph spanning page 6, line 17 to page 7, line 7 provides the only disclosure of the use of the apparatus of the instant invention. Assuming that the stimulator unit 21 is consistent with the claimed combination probe, transceiver and power source, the disclosure only provides that a woman removes the stimulator unit from a holder or case 28 and that "the stimulator unit 21 is then inserted into the vagina." There is no explicit disclosure how the stimulator unit is inserted into the vagina, i.e. whether a tool is used or not. It is entirely possible in view of this passage that a tool, such as an applicator tube, is used to insert the unit 21 into the vagina. Therefore, this limitation comprises impermissible new matter.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-13, 16, 17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "non-implanted" recited in line 4 of claims 1 and 16 renders the claims indefinite. No special definition of the term is set forth in the specification of the instant application. Moreover, the disclosure does not state or clearly suggest that the limitation "non-implanted" as used in the present

application is intended to be interpreted in light of the FDA definition of the term "implant." Therefore, one cannot be certain of the metes and bounds of this term, which is a negative limitation, and thus the scope of the aforementioned claims.

In the *Tenth Edition of Merriam Webster's Collegiate Dictionary (1996),* the verb "implant" is defined as "to insert in a living site." *Dictionary.com Unabridged (v 1.1)* defines the verb "implant" as "3. *Medicine/Medical.* To insert or graft (a tissue, organ, or inert substance) into the body." *Stedman's Medical Dictionary, 27th Edition* (2000) defines "implant" to mean "1. (im-plant') To graft or insert." In view of these "dictionary" definitions of the word "implant," the limitation "non-implanted," or essentially *not inserted* in a living site, used in the claims of the present invention would appear to contradict subsequent limitations of the claims that require the device to be inserted into and contained within the vagina in order to monitor vaginal conditions, and therefore render the claimed apparatus inoperable. The Examiner further respectfully submits that the context of the term "non-implanted" cannot be determined from the claim language, as even an implant may "non-implanted" before it is inserted within the living body.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the

international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-7, 11-13, 16, 17 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehrotra et al. ('859). Mehrotra et al teach a vaginal probe for monitoring various conditions within the vagina of a mammal. It is well known that humans are mammals. The probe includes at least a single, separate unit (see Figure 1) in the form of a portable and non-implanted combination probe (18) which integrates a transceiver (see column 8, lines 38-39), an antenna (see column 3, line 66 - column 4, line 3; column 4, lines 50-59; column 7, lines 23-28; and column 8, lines 34-43) and a power source (see column 4, lines 30-34 and column 7, lines 18-20). The probe communicates with a separate unit in the form of a combination controller and transceiver (receiver station/computer, see at least column 8, lines 43-53 and column 9, lines 8-16) that sends control signals to the probe to alter the transducing sensors (e.g. turning selected sensors off and on) and receives output signals from the probe and communicates with external networks, devices or databases. The single, separate controller and transceiver unit may be handheld for forming a wireless signal feedback loop with the probe unit. The probe unit is adapted to transduce vaginal conditions using a plurality of sensors (see at least column 7, lines 9-13 and column 8, lines 28-33) mounted on the probe. The sensors may be used to sense body temperature, the pH of cervical fluids and conductivity (means for sampling vaginal fluid), and motion and heart rate (which are inherently representative of muscle contractions). Other types of sensors may be used. In another embodiment the probe may be adapted for medication delivery (see column 6, lines 6-8). The probe (18) is an intravaginally containable sealed unit that may be inserted "in-situ" into the vaginal vault or removed therefrom. The probe (18) may be made of plastics or metals such that

it is not expandable or compressible. In operation, the probe unit is capable of being self-inserted by a human subject into the human vagina without the use of a tool.

9. Claims 1-7, 11-13 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Guice et al. ('390). Guice et al. teach a system and method for monitoring the health and status of livestock and other animals. The system includes at least a single, separate unit (50,51,280) in the form of a portable, intravaginally containable combination probe, transceiver and power source in a single, separate unit (70,72) in the form of a combination controller and transceiver. The use of the transitional term "comprising" in the claim language is inclusive or open-ended and does not exclude additional, unrecited elements (i.e., in addition to the claimed two "single, separate units"). See MPEP 2111.03. The single, separate unit (50,51,280) in the form of a portable, intravaginally containable combination probe, transceiver (see at least paragraph [0124]) and power source (288) is "non-implanted" in a substantially equivalent sense as the limitation is defined in the specification of the instant application (i.e., "intravaginally containable... in situ yet removable" as recited in paragraph [0010]), although the patentee has chosen to call his telesensor an "implant." The Guice implant embodiments of Figs. 18 and 19 (see paragraph [0179]) are in the form of spring-like curved members that can be compressed to a smaller diameter to be inserted into a vaginal cavity, then expand to a larger diameter after being inserted into the vaginal cavity, and are provided with tabs (299) or a wire member (301) to aid in removal of the telesensor implant without the need for incisions or surgery. The probes of Guice et al. (Figures 17-19) are not disclosed as being expandable or compressible along the width of the outer surface of the housing.

The combination probe, transceiver and power source of Guice et al. is provided with means for sensing vaginal conditions (292) and 2-way wireless communication means for transmitting information that is transduced and for receiving control and programming signals (see at least paragraph [0124]). The separate combination controller and transceiver is provided with wireless means for sending signals to the probe and for receiving signals therefrom (see at least paragraph [0209]). A wireless signal feedback loop is provided between the controller and the probe and which may be an interactive or closed signal feedback wireless loop. The probe is a sealed unit which is inserted "in-situ" into the vaginal vault or removed therefrom (see at least paragraph [0135]). The means for sensing vaginal conditions of the probe include sensor transducers (292) that may be provided with means for transducing in the form of a muscle activity sensor (see at least paragraph [0080]); means for sampling temperature changes (see at least paragraph [0106]) in the vaginal environment. The wireless combination controller and transceiver includes means for wirelessly altering operation settings of the probe and means for wirelessly altering the transducing sensor (see at least paragraph [0104]). A wireless means (72) is provided to transmit signals and/or receive signals from external devices, networks, or databases. The controller may be inclusive of a hand-held unit (e.g., a PDA). The probes (Figs. 17-19) of Guice et al. are capable of being self-applied by a human subject into the human vagina such that vaginal conditions are transduced by the probe.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eini et al. ('037) in view of Mehrotra et al. ('859).

Eini et al. teach a system (50) including a device (10) for electrically stimulating and for sensing electrical activity of muscles and nerves defining the vaginal cavity. The device includes a non-implanted combination probe (10) and control unit (20) that is provided with means for sensing vaginal conditions and stimulating perineal musculature and nerves. The control unit (20) is effectively a transceiver as it includes means for transmitting (26) and means for receiving (28) signals. The control unit (20) includes a battery to power the device (column 8, lines 5-6). The device (10) includes a sensor body (12) mounted and secured to the control unit (20) to form a single, combination probe and transceiver unit. *The American Heritage® Dictionary of the English Language, Fourth Edition* (2004) defines the verb "integrate" as "1. To make into a whole by bringing all parts together; unify. 2a. To join with something else; unite." Therefore, the combination device (10) of Eini et al. integrates a transceiver and a power source. The transceiver of the control unit is provided with 2-way wireless communication means (26/28) for transmitting information that is transduced and for receiving control and

programming signals. The system (50) further includes a separate combination controller (52) and a transceiver comprising means for sending signals to the probe and for receiving signals therefrom (54/58). A wireless signal feedback loop is provided between the controller and the probe. The controller (52) includes means for wirelessly altering operation settings of the probe. The probe is a sealed unit that is provided with means for transducing changes in the vaginal environment in the form of a muscle contraction sensors and stimulators (24). The controller can be a hand-held unit that can wirelessly alter stimulation signal levels at the probe. The stimulators on the probe include means for automatic adjustment of stimulation levels in response to sensed muscle contractions and changes in the vaginal environment and can be programmed to provide increasing stimulation over a given period of time. Eini et al. teaches all of the limitations of the claims, but lacks an express teaching that the vaginal probe unit includes an antenna.

Mehrotra et al., as discussed hereinabove, teach a combination probe, transceiver, antenna and power source that uses any of a variety of sensors to monitor conditions within the vaginal cavity.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide the transceiver in a probe similar to that of Eini et al. with an antenna similar to that of Mehrotra et al. in order to facilitate the wireless communication between the vaginal probe and the remote, external unit as a means to send and receive radio signals or electromagnetic waves.

12. Claims 1-7 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blythe ('118) in view of Mehrotra et al.

Blythe teach a vaginal probe for monitoring various conditions within the vagina of a human or animal. The probe includes at least a single, separate unit (10) in the form of a portable, non-implanted, and intravaginally containable combination probe and power source (68). The probe communicates with a separate unit in the form of a computer (75) that sends control signals to the probe to alter the transducing sensors (e.g. turning selected sensors off and on) and receives output signals from the probe (see column 7, lines 16-19) via a connection at interface port (72) and communicates with external networks, devices or databases. In one embodiment, the computer is eliminated to make the probe unit portable. In this embodiment, the probe is a single separate unit in the form of a combination probe (10), transponder (92), and power source (68). The wireless combination probe (10) may be provided without the interface port (see column 8, lines 31-34). The probe unit is adapted to transduce vaginal conditions using a plurality of sensor transducers (42,44,46,48,50,52,56,58) mounted on the probe. The sensors may be used to sense body temperature, the pH of cervical fluids, Luteinising Hormone levels in vaginal fluids, cervical mucus density, estrogen levels, progesterone levels, estradiol levels, and vaginal cavity pressures which are inherently representative of muscle contractions (see column 2, lines 23-29 and 41-44). Other types of sensors may be used (see column 2, line 44). In another embodiment the probe may be adapted to apply treatment material for a condition (medication) such as semen or fertilized eggs to patients suffering from fertility issues (see column 9, lines 7-13). The probe is a sealed

unit that may be inserted "in-situ" into the vaginal vault or removed therefrom. Nothing in the disclosure of the Blythe patent suggests that the probe is either expandable or compressible. In operation, the probe unit may be self-inserted by a human subject into the human vagina (see column 7, lines 9-11). Blythe teaches all of the limitations of the claims except that the probe unit and controller unit include transceivers that provide a two-way wireless signal feedback loop between the combination probe unit and the combination controller unit.

Mehrotra et al., as discussed hereinabove, teach a combination probe, transceiver and power source that uses any of a variety of sensors to monitor conditions within the vaginal cavity of a mammal and forms a two-way wireless signal feedback loop with a combination controller and transceiver in order to control operation of the probe sensors and allow signals generated thereby to be received and analyzed at the external combination controller and transceiver unit to form a truly portable unit.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention to provide an intravaginal probe that is self-inserted into the human vagina by a human subject similar to that of Blythe with transceivers similar to those of Mehrotra et al. in place of the computer interface and transponder of Blythe in order to make the probe fully portable by forming a two-way wireless signal feedback loop between the probe unit and the controller unit, enabling control of the sensors on the probe unit and transmission of signals generated by the sensors on the probe unit to the external controller unit for analysis.

Response to Arguments

13. Applicant's arguments regarding the rejection of claims 1 and 14 under 35 USC 112, first paragraph, with respect to the limitation "*self-applied by a human subject into the human vagina*" are persuasive in view of the claim amendments removing this limitation from the claims. The rejection of claims 1 and 14 under 35 USC 112, first paragraph, has been withdrawn.

14. Applicant's arguments filed March 22, 2006 with regard to the rejection of claim 16 under 35 USC § 112, first paragraph, have been fully considered but they are not persuasive. Applicant contends that page 5, line 15 of the specification supports the limitation "non-expandable and non-compressible in cross-section" as the material of the unit is formed of polycarbonate which is known to be a very hard material. However, a review of the patent literature reveals that polycarbonate can be both expandable and compressible. U.S. Patent Application Publication No. 2006/0264982 recites that polycarbonate is a "semi-rigid and resilient" material (see paragraph [0017], lines 6-8). U.S. Patent Application Publication No. 2006/0247657 teaches that an expandable balloon member may be formed of polycarbonate (see paragraph [0049]). Such a polycarbonate balloon would be at least expandable in cross section. U.S. Patent Application Publication No. 2006/0161154 teaches that polycarbonate is a compressible material (see paragraph [0042]). In view of the foregoing, the recitation at page 5 of the specification that the probe may be made of polycarbonate is not sufficient support for the claim limitations requiring the probe to be "non-expandable and non-compressible in

cross-section" absent any express disclosure of those characteristics in the original specification. Therefore, these limitations are considered new matter, and the rejection of claim 16 under 35 USC 112, first paragraph, is maintained.

15. Applicant's arguments filed March 22, 2006 with regard to the rejection of claim 17-19 under 35 USC § 112, first paragraph, have been fully considered but they are not persuasive. Applicant contends that the sentence bridging pages 6 and 7 "where it is stated that the stimulator unit 21 is then inserted into the vagina (similar to a tampon)" and the language on page 6 that "the end 24 of the unit 21 is rounded to facilitate insertion" are self-evident that insertion is accomplished without a tool. The Examiner respectfully disagrees. The two passages cited by Applicant do not provide any clear disclosure as to whether or not a tool is used to insert the unit. The first passage cited by Applicant merely discloses that the unit is "inserted into the vagina" and is silent as to how this is accomplished. The Examiner notes that the sentence bridging does not relate the insertion of the unit to that of a tampon; however, it is common knowledge that tampons are often inserted using a telescopic applicator which may be considered a "tool." Furthermore, the shape of the end of the unit has no bearing on whether a tool is used to insert the unit or not. It is entirely possible in view of the original disclosure of the instant application that a tool can be used to insert the unit 21 into the vagina. Since there is no explicit disclosure in the application as originally filed as to how the stimulator unit is inserted into the vagina, i.e. whether a tool is used or not, the claim limitation "without the use of a tool" is considered impermissible new matter. Therefore, the rejection of claims 17-19 under 35 USC 112, first paragraph, is maintained.

16. Applicant's arguments filed March 22, 2006 with regard to the rejection of claims 1-13, 16, 17 and 19 under 35 USC § 112, second paragraph have been fully considered but they are not persuasive.

Applicant contends that "non-implanted" is precisely an appropriate and proper term pursuant to FDA guidelines and requirements. Applicant further contends that the term "non-implanted" is the term of the art in the pertinent field, and is therefore definite, requires no definition since it is the term prescribed by the FDA, and is thus recognized by those in the industry to have specific metes and bounds. Applicant finally contends that the non-technical and non-medical Tenth Edition of Merriam Webster's Collegiate Dictionary (1996) is hardly a proper reference to determine the definition of the word "implant" as understood in the medical field. These arguments remain not persuasive.

The Examiner respectfully maintains the position that the FDA and the USPTO are different government agencies, and that metes and bounds of terminology required by one of those agencies is not necessarily applicable to the other. The Examiner points to the first sentence of the third paragraph of the FDA approval letter filed by Applicant on March 28, 2005 as Exhibit 3 in support of his position. The Examiner acknowledges the exhibits previously submitted by Applicant in support of Applicant's arguments, but respectfully notes that at no point does specification of the instant application direct one to definitions provided by the FDA for interpretation of the meaning of the term "non-implanted." The claim limitations are to be given their broadest reasonable interpretation absent any special definitions for the claim terminology set forth in the specification. Therefore, one must acknowledge that there are many definitions that may correspond to

the term "implant" as used in the claim limitation "non-implanted." The definition of the term "implant" provided by the FDA and cited by Applicant in the remarks is directed to a noun. However, the term "non-implanted" as used by Applicant in the claims is an adjective that is used to modify a noun. Since Applicant's usage of the term is not consistent with the usage of the FDA, one cannot be certain that the definition of "non-implanted," as used by Applicant, corresponds to and is consistent with the definition of the term "implant" provided by the FDA.

While Applicant alleges that the Examiner has incompletely cited the "dictionary" definition of the term "implant," the Examiner respectfully submits that the parenthetical text following the cited definition which Applicant alleges to be the "complete 'dictionary' definition" is merely an example of the cited definition. The definition "to insert in a living site or living tissue" cited by the Examiner is consistent with the two "medical definitions" provided by the Examiner hereinabove from Dictionary.com and Stedman's Medical Dictionary, 27th Edition. The Examiner respectfully submits that at least Stedman's Medical Dictionary, 27th Edition is a "proper" reference to determine the scope of the meaning of the term as understood in the medical field. As noted above Stedman's Medical Dictionary defines the term "implant" to mean "to graft or insert." As Applicant has pointed out in the Remarks dated March 22, 2006, "the term 'non-' is defined as 'a prefix meaning **not**.' Given that the medical definition for implant as defined by Stedman's Medical Dictionary is "to insert," it is unclear how the probe unit 21 of Applicant's invention can be located in the vaginal cavity if it is *not inserted* therein.

The Examiner maintains the position that absent any special definition of the term set forth in the specification of the instant application, one cannot be certain of the scope of this negative limitation. The Examiner respectfully submits that the specification of the instant application does not point one to the FDA for a definition of the term "non-implanted." Furthermore, the Examiner contends that even one of ordinary skill in the medical arts would recognize that a device that is an "implant" as defined by the FDA may be considered "non-implanted" as required by the claim limitations of the instant application, before said device is surgically inserted into the body of a patient.

In view of the foregoing, the Examiner maintains the position that one cannot be certain of the metes and bounds of this limitation and thus the scope of the aforementioned claims. The rejection of claims 1-13, 16, 17 and 19 under 35 U.S.C. 112, second paragraph, as being indefinite is maintained.

17. Applicant's arguments filed March 22, 2006 with regard to the claim rejections under 35 USC § 102(e) citing Mehrotra et al have been fully considered but are not persuasive.

Applicant first contends that Mehrotra et al does not teach or suggest a combination probe that integrates a transceiver, antenna, and power source. The Examiner respectfully disagrees. Column 8, lines 34-43 of the Mehrotra et al patent disclose an embodiment where a transceiver and antenna are housed in a device that is received within the vagina. Column 7, lines 18-21 of the Mehrotra et al patent recite that the device includes a battery for powering the electronic components. *The American*

Heritage® Dictionary of the English Language, Fourth Edition (2004) defines the verb "integrate" as "1. To make into a whole by bringing all parts together; unify. 2a. To join with something else; unite." In view of the foregoing, the probe of Mehrotra et al can be said to integrate a transceiver, antenna and battery. Even in those embodiments such as that illustrated in Figure 1 of the Mehrotra et al patent, where the antenna is disposed in an inflexible arm, the arm, antenna and transmitting means are joined or united with the remainder of the probe such that the probe can be said to integrate a transceiver and antenna. In response to Applicant's argument that the Mehrotra et al reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a probe containing no external means for transmitting and/or receiving information) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The probe of Mehrotra et al is also a self-contained unit.

Applicant next argues that Mehrotra et al fails to teach or suggest a probe which integrates a transceiver, antenna and power source for receiving control and programming signals. The Examiner respectfully disagrees. Column 8, lines 34-43 of the Mehrotra et al patent teach that the probe and a remote receiver station both may include transceivers. *Newton's Telecom Dictionary, 18th Edition* (2002) defines a "transceiver" as "any device that transmits and receives." Therefore, both the probe and remote receiver station of Mehrotra et al have the capability of transmitting and receiving signals. Column 8, line 54 - column 9, line 17 of the Mehrotra et al patent disclose that the receiver station may

query the probe to receive data on demand. These query signals may be interpretted as either control or programming signals.

Finally, Applicant contends that the Mehrotra et al device is clearly not directed to any "mammal" and is limited to tailed animals. While the preferred embodiment of the Mehrotra et al patent is clearly directed to use in cows, the detailed description of the patent clearly discloses use in "mammals" without expressly excluding use in humans. The probe of Mehrotra et al would be fully operable without a tail-securing means as disclosed in some preferred embodiments of the Mehrotra et al patent. The Mehrotra et al patent is silent as to the particular dimensions of the device such that it cannot be argued that the probe of Mehrotra et al is of a size that prevents it from being inserted in a human vagina. Moreover, the bulk of the probe of the preferred embodiment of Mehrotra et al is a cylinder similar to the probe of the instant application. Therefore, the probe of Mehrotra et al appears fully capable of use in a human vagina.

In view of the foregoing, the rejection of claims 1-7, 11-13, 16, 17 and 19 under 35 U.S.C. 102(e) as being anticipated by Mehrotra et al. ('859) is maintained.

18. Applicant's arguments filed March 22, 2006 with regard to the claim rejections under 35 USC § 102(e) citing Guice have been fully considered but they are not persuasive. Applicant contends that the Guice reference is not adapted to be inserted into a human vagina and alleges that the Examiner merely states that the Guice device would be capable of being used in the human vagina but provides no basis therefor. These arguments are not persuasive.

Applicant contends that the limitation "adapted to be inserted into the human

vagina" need not result in a structural difference between the claimed invention and the prior art in order to be considered a distinguishing limitation. The Examiner respectfully disagrees. The limitation "adapted to be inserted into the human vagina" is clearly directed to the intended use of the apparatus of the present invention. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Contrary to Applicant's assertion that the Examiner provides no basis for the capability of the Guice device being used in a human vagina, since the Office Action of December 16, 2004, the Examiner contends that there is nothing in the structure of the Guice probes that would prevent the probes from being inserted into the human vagina and operated in the claimed fashion. That is the Guice probes appear dimensioned such that they are capable of being inserted into the human vagina, irregardless of whether or not the FDA approves or whether it would be advisable to do so. The probes of Guice are formed of biocompatible materials. Once disposed with a human vagina, a Guice probe would be *capable* of functioning properly to sense or transduce vaginal conditions, such as the temperature of vaginal walls or a general temperature within the interior of the vaginal cavity, particularly considering that the claims fail to require the probe to engage the interior of the vagina in any particular manner.

Regarding Applicant's argument that the Guice patent fails to teach a combination probe that is "non-implanted," this argument is not persuasive at least due to the indefinite nature of this limitation. The Examiner submits that the claim language is

unclear as to the context in which the probe is "non-implanted." Irregardless of whether or not the probes of Guice are "implants" (the Examiner still does not concede that they are), the probes of Guice will still meet the "non-implanted" limitation before they are inserted into the body. Given that the verb "implant" is defined by Stedman's Medical Dictionary to mean "to graft or insert," Applicant's probe may also be considered to be "implanted" since it must be *inserted* in order to be disposed with the vagina making this limitation an inappropriate limitation to define the claimed invention. Applicant is respectfully referred to previous Office actions for additional reasons why this "non-implanted" limitation does not define over the Guice reference.

Regarding claims 17-19, Applicant argues that the use of a tool to insert a device precludes a device from being called "non-implanted." The Examiner respectfully disagrees. Many well known gynecological, intravaginal devices that are not considered implants by the FDA utilize tools for applying the device. Among such devices are cytological samplers which use a tool to form a pathway into the vaginal canal and tampons which use a telescopic tool for application or insertion. It is believed that at least tampons are not considered implants, particularly in view of the definition provided by the FDA. However, the limitations in claims 17-19 expressly stating the probe is inserted without the use of a tool are considered new matter as discussed in detail hereinabove.

In view of the foregoing and the arguments presented in the Examiner's previous Office Actions, the rejection of claims 1-7, 11-13 and 16 under 35 U.S.C. 102(e) as being anticipated by Guice et al. ('390) has been maintained. The addition of claim 16 to the statement of the grounds of the Guice et al. rejection set forth above, merely corrects a

typographical error in the Non-Final Office action of December 22, 2005. The limitations of claim 16 are clearly addressed in the rejection citing Guice set forth therein.

19. Applicant's arguments filed March 22, 2006 with regard to the claim rejections under 35 USC § 103(a) citing the combination of Eini et al. and Mehrotra et al. have been fully considered but they are not persuasive. Applicant contends that Mehrotra et al. is not analogous art and that Eini et al. includes an antenna that is external to the unit. These arguments are not persuasive. As clarified in the rejection set forth hereinabove, Mehrotra et al. is cited to show that it is known, if not inherent, to combine an antenna with a transceiver to enable wireless communication between a vaginal probe and a remote unit. The invention of Eini et al, the invention of Mehrotra et al, and the instant invention may be considered analogous art as they all are pertinent to the same problem of sensing vaginal conditions of mammals and wirelessly communicating the sensed conditions with a remote unit. Regarding the argument that the antenna and power source are external to the unit, the argument is not persuasive as the sensor body (12) secured to the control unit (20) can be considered a single combination probe that integrates a transceiver (antenna) and power source. The claim limitations do not require that the entire probe be intravaginally contained nor preclude the power and tranceiver unit from being positioned outside of the vaginal cavity. In view of the foregoing, the rejection of claims 8-10 under 35 U.S.C. 103(a) as being unpatentable over the combination of Eini et al. and Mehrotra et al. is maintained.

20. Applicant's arguments filed March 22, 2006 with regard to the claim rejections under 35 USC § 103(a) citing Blythe in view of Mehrotra et al have been fully considered but they are not persuasive. Applicant contends that Blythe has an external probe portion in contrast to Applicant's invention; that neither of the references is analagous art; that the proposed modification or combination of the cited references would change the principle of the operation of the prior art being modified; and that there is no motivation or suggestion to combine the references.

In response to applicant's argument that the Blythe reference has an external probe portion in contrast to Applicant's invention, it is noted that the rejected claims do not recite limitations excluding the possibility of an external probe portion. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that neither reference is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the Blythe reference is clearly analogous art as it relates to sensing vaginal conditions of a human and/or animal. While the Mehrotra et al reference is preferably directed to veterinary uses, there is nothing in the Mehrotra et al reference that expressly limits the disclosed use in "mammals" to exclude use in humans. Although Applicant contends that

neither reference is in the same field of endeavor as Applicant's device, as the cited references allegedly deal with veterinary devices which is "borne out by the great differences in the PTO classifications given the various devices," the Examiner notes that class 600, Diagnostic Testing, where the instant application is primarily classified does not distinguish between human and veterinary applications. Accordingly the cited references are reasonably pertinent to the particular problem with which Applicant was concerned, as all relate to transducing and/or affecting vaginal conditions.

Regarding Applicant's suggestion that the proposed modification or combination of the cited references would change the principle of operation of the prior art invention being modified, the Examiner notes that Applicant has not provided any reasoning to support this assertion. Since the proposed combination or modification would not apparently change the principle of operation of either prior art invention, i.e. the wireless monitoring of vaginal conditions, this argument is not persuasive.

Regarding Applicant's argument that there is no suggestion or motivation the references to combine the cited references, the prior art itself is not required to provide a teaching, suggestion or motivation that would lead one of ordinary skill in the art to combine prior art elements in the manner claimed in the application before holding claimed subject matter to be obvious. *KSR Int'l Co. v. Teleflex, Inc.*, No 04-1350 (U.S. Apr. 30, 2007). Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention to provide an intravaginal probe that is inserted into the human vagina by a human subject similar to that of Blythe with transceivers similar to those of Mehrotra et al. in place of the computer interface and transponder of Blythe in order to make the probe fully portable by forming a two-way wireless signal feedback

loop between the probe unit and the controller unit, enabling control of the sensors on the probe unit and transmission of signals generated by the sensors on the probe unit to the external controller unit for analysis.

In view of the foregoing, the rejection of claims 1-7 and 11-19 under 35 U.S.C. 103(a) as being unpatentable over Blythe in view of Mehrotra et al is maintained.

21. The declarations under 37 CFR 1.132 filed March 22, 2006 are insufficient to overcome the rejection of claims 1-7, 11-13 and 16 under 35 U.S.C. 102 (e) based upon Guice et al. as set forth in the last Office action. The Examiner acknowledges with respect and admiration the professional and educational accomplishments of Dr. Jayne and Dr. Wharton, and recognizes their respective degrees of expertise in their respective fields. However, the declarations submitted refer only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness/non-anticipation is commensurate in scope with the language of the pending claims. See MPEP Section 716. While both declarations show that it is not advisable by those skilled in the art to use the Guice device as claimed, both declarations fail to set forth facts that sufficiently prove that the Guice implant units are not *capable* of use in a human. Both declarations attempt to point to several teachings from the Guice reference as evidence that the Guice implant units are not acceptable for human use and are not "non-implanted" devices. However, the teachings of Guice (e.g., the use of adhesives and tools to install the implant units) pointed to by Dr. Jayne and Dr. Wharton are not necessarily requirements of all embodiments of the Guice system as evident from the disclosure of paragraph [0042] of

the Guice reference. The declaration of Dr. Jayne further repeatedly states that FDA standards and regulations and safety concerns support that the implant units of Guice may not be used in a human vagina; however, the declaration still fails to provide factual evidence to support that the Guice device is not *capable* of being used in the human vagina, irregardless of whether it is advisable to do so. More specifically, there is no factual evidence provided in the declaration, for example relating to the dimensions, composition, or configuration of the device that clearly show that the device of Guice is incapable of being inserted in the human vagina in an operable fashion. The declarations merely provide repeated statements that the FDA would not approve and that there are clear anatomical differences between humans and livestock although the declarations are silent as to how these anatomical differences would prevent the device of Guice from being inserted into the human vagina. The declarations ultimately only show that the Guice device would be unlikely to get FDA approval, is not advisable to be used in humans, and that one skilled in the art is unlikely to look to the Guice reference for a teaching or suggest with respect to how to use or configure a device to be used temporarily, in a non-implanted manner, in the human vagina. The lack of factual evidence provided in the declarations of Dr. Jayne and Dr. Wharton indicating that the structure of the instant invention, as defined by the language of the pending claims, patentably defines the structure of the present invention over that of the Guice reference is insufficient to overcome the rejection of claims 1-7 and 11-13 under 35 U.S.C. 102(e) as anticipated by Guice et al.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of non-anticipation and nonobviousness fails to outweigh the evidence of anticipation.

Conclusion

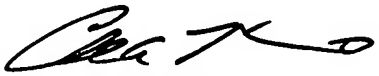
22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mamberti-Dias ('422) teach a vaginal or anal endocavity probe that uses telemetry. Gafni ('030) teaches a vaginal probe with wireless embodiments. Hogaki et al. ('745) teach a fetus monitor. Seike et al. ('537) teach a parturition alarm device. Zartman ('077) teach a device for temperature measurement of female animals. McCreesh et al. teach vaginal temperature sensing using UHF radio telemetry. Blachetta ('363) teaches a body fluid conductivity meter with remote control. Hovland et al. ('914) teaches devices for monitoring female arousal with wireless embodiments.

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

24. Any inquiry concerning this communication should be directed to Charles A. Marmor, II at telephone number (571) 272-4730.



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